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a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

[44 FR 22348, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the center of FDA responsible for a matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Division of Dockets Management the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Division of Dockets Management on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Division of Dockets Management

shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Division of Dockets Management as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the center and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the center, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

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(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in § 12.70.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985]

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of § 10.55 relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the center responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

[44 FR 22348, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Division of Dockets Management under § 10.20.

(b) The person making a submission shall serve copies of it on each participant in the proceeding, except as provided in §§ 13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph (d) of this section, or similar document must be.

(c) A submission must be mailed to the address shown in the notice of appearance or personally delivered.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §§ 13.10(b)(2) and 13.45.

(f) A participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis in the form and manner specified in § 12.82.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 13.5, the director of the center responsible for the matters involved in the hearing must submit to the Division of Dockets Management—

(1) The relevant portions of the existing administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record;

(2) A list of all persons whose views will be presented orally or in writing at the hearing;

(3) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. *Files* means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted;

(4) All other documentary information relied on; and

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under § 13.5, each participant shall submit to the